PUBLIC AVAILABILITY OF FOOD ADDITIVE PETITIONS

Much of the information contained in a food additive petition is available for public disclosure under 21 CFR 571.1(h). It is unlikely, however, that many requests for this type of information will be received. Rather than routinely purging all food additive petitions for this purpose, a paragraph will be added to the FEDERAL REGISTER approval announcement (see Attachment A) stating that those individuals wishing to examine the petition should request an appointment. The petition and accompanying documents will be purged only after such a request has been received.

1. **Purpose:**

   This guide describes the procedures to be used when making food additive petitions (FAP) available for public disclosure.

2. **Procedures:**

   The procedures to be followed are:

   a. The contact person named in the FEDERAL REGISTER announcement will be identified as the person with whom an appointment should be made.

   b. The contact person will be responsible for arranging an appropriate place where the file may be reviewed.

   c. The contact person shall coordinate with the Center's Freedom of Information Coordinator, Office of Management and Communications (HFV-12) to determine the information required to be purged from the file prior to disclosure.

   d. Information, submitted under 21 CFR 570.17, exemption for investigational use of a food additive, shall be handled in accordance with the provisions of 21 CFR 514.12.

3. **References:**

a. Title 18, United States Code, Section 1905.

b. Federal Food, Drug, and Cosmetic Act, Section 301(j)(21 USC 331(j)). This section prohibits FDA staff from divulging methods or processes which are entitled to protection as trade secret.

c. Code of Federal Regulations, Title 21.

(1) Commissioner's Delegation of Authority to disclose official records and information, 21 CFR 5.23 and FDA Staff Manual Guide FDA 1410.7.

(2) Public Information, 21 CFR Part 20.

(3) Food Additive Petitions, 21 CFR 571.1(h).

(4) New Animal Drug Applications, 21 CFR 514.11 and 514.12.

STANDARD FORM PARAGRAPH
(to be included in the preamble to all
final FAP FEDERAL REGISTER announcements)

In accordance with Section 21 CFR 571.1(h), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Veterinary Medicine (address above) by appointment with the information contact person listed above. As provided in 21 CFR 571.1(h)(2), the Agency will remove from the documents any materials that are not available for public disclosure before making the documents available for inspection.